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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,236	06/27/2001	Jeffrey H. Burbank	265/022	5534

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EXAMINER	
BIANCO, PATRICIA	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,236	BURBANK ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 14 & 15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. The amended claim language of "**said step of connecting including closing a single engagement element of said blood treatment machine, such that all of said waste, replacement fluid, and said blood withdrawal lines are engaged with said at least one pump in a single step**" is now critical or essential to the practice of the invention, but not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The disclosure as originally filed does not provide support for the new step as recited, nor does it provide proper antecedent basis, "a single engagement element" as now claimed. These amendments are new matter, and as such should be deleted from the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 7, 10, 11 & 14 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Falkvall et al. (5,730,712). Falkvall discloses an extracorporeal blood treatment apparatus and method of using to perform hemofiltration. The method of treating blood removed extracorporeally from a patient via hemofiltration comprises the steps of withdrawing blood through a withdrawal line at a rate of 400 mL/min or more, passing the blood through a filter, and returning the blood to the patient after treatment through a blood return line. This system and method allows for a urea clearance of 225 to 300 mL/min at this rate. With respect to claims 2, 6, & 10, the steps of repeating the procedure at least four times a week, at least daily, and for more than one week would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, the modifying of these steps for an individual's treatment schedule would depend on each patient and therefore vary on a per patient basis. With respect to claim 3, the recitation that the filter be disposable has not been given patentable

weight since anything, if desired, can be disposable. With respect to claim 4 requiring the blood withdrawal and return lines and filter being pre-attached, it would have been obvious to one having ordinary skill in the art to use a cassette having pre-attached tubing and a filter since it has long been known in the art to use such cassette members for extracorporeal blood treatment procedures. With respect to claim 7, the step of conducting the procedure at home would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, if home treatment is prescribed for a patient because it is deemed beneficial by the treating physician, this step would be determined on a per patient basis. With respect to claim 14, the use of a peristaltic pump for blood withdrawal and return would have been an obvious choice of a pump since it is known in the extracorporeal blood treatment art to use peristaltic pumps for blood withdrawal and return to a patient and Falkvall discloses that the filter is used with extracorporeal blood treatments.

Claims 1-11 & 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (5,536,412). Ash teaches of a hemofiltration system and method for using comprising a patient connection including blood withdrawal and return lines, a filter, a replacement/infusate fluid tank and delivery line, a pump, a blood particle sensor in the return line, and a sensor in the infusate line. The system pump rate is from 200 mL/min to 600 mL/min to achieve the desired clearance rate of 225 to 300 mL/min at this rate. The reservoir for infusate holds at least 1.5L of liquid. Ash has a computer for monitoring the blood flow rate and amount of infusate delivered to the patient. With

respect to claims 2, 6, & 10, the steps of repeating the procedure at least four times a week, at least daily, and for more than one week would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, the modifying of these steps for an individual's treatment schedule would depend on each patient and therefore vary on a per patient basis. With respect to claim 3, the recitation that the filter be disposable has not been given patentable weight since anything, if desired, can be disposable. With respect to claim 4 requiring the blood withdrawal and return lines and filter being pre-attached, it would have been obvious to one having ordinary skill in the art to use a cassette having pre-attached tubing and a filter since it has long been known in the art to use such cassette members for extracorporeal blood treatment procedures. With respect to claim 7, the step of conducting the procedure at home would have been obvious to one having ordinary skill in the art since, lacking any criticality in the specification, if home treatment is prescribed for a patient because it is deemed beneficial by the treating physician, this step would be determined on a per patient basis. With respect to claim 14, the use of a peristaltic pump for blood withdrawal and return would have been an obvious choice of a pump since it is known in the extracorporeal blood treatment art to use peristaltic pumps for blood withdrawal and return to a patient and Ash discloses that the filter is used with extracorporeal blood treatments. Ash discloses that there are various sensors, including blood sensors and flow sensors in the lines that communicate with the computer of the system. Ash further discloses that there are empty line sensors on all fluid-filled lines, which inherently includes the replacement fluid line (claim 14) (See col. 10, lines 3-35).

Claim 13 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (5,536,412) in view of Kitaevich et al.(5,211,849). Ash discloses the invention substantially as claimed, see rejection above, however, fails to disclose specifically that the computer (controller) has an alarm that activates when the difference between the blood flow rates exceeds a predetermined level.

Kitaevich et al. discloses a hemofiltration system and method including a controller and multiple sensors that send signals to said controller. One such sensor is a pressure transducer in the tubing to measure pressure (i.e. blood flow pressure). From the signals, the controller determines the actual blood flow pressure and determines if it is within or outside of the pressure limits. If it exceeds the preselected limits an alarm sounds (col. 6, lines 25-65). At the time of the invention it would have been obvious to one having ordinary skill in the art to modify the controller of Ash to include an alarm function as taught by Kitaevich et al., since it is important to monitor and be alerted to high blood flow rates.

Claim 12 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over Ash as applied to claim 1 above, and further in view of Loiterman et al. (5,041,098). Ash **discloses** the invention substantially as claimed, see rejection supra. Ash, however, fails to disclose specifically that the withdrawal and return lines are via a subcutaneous port.

Loiterman teaches of an implantable vascular access port that may be use din hemofiltration treatment systems. At the time of the invention, it would have been obvious to use an implantable vascular port in the process of Ash as taught by Loiterman. Use of an implantable port allows for easy connection and disconnection of the patient's vascular system to the hemofiltration system at each treatment.

Response to Arguments

Applicant's arguments filed 2/19/04 have been fully considered but they are not persuasive. Applicant argues that the amendment to claim 1, and thereby its dependents, overcome the rejections of Falkvall et al. and Ash. The amendments made to claim 1 have been rejected under 35 USC 112, first paragraph, and are an addition of new matter. See rejection below. Therefore, the rejections for claim 1 and its dependents stand. With respect to claims 13 & 16, applicant argues that the office action did not provide a basis for the rejection of these claims. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Further, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 13th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762

PATRICIA BIANCO
PRIMARY EXAMINER